US 20170325949A1

(19) **United States**

(12) **Patent Application Publication** (10) **Pub. No.: US 2017/0325949 A1**

Rodgers et al. (43) **Pub. Date: Nov. 16, 2017**

(54) **HEART VALVE IMPLANT AND METHODS FOR DELIVERING AND IMPLANTING SAME**

(71) Applicant: **Cardiosolutions, Inc.**, Bridgewater, MA (US)

(72) Inventors: **Richard Rodgers**, Hudson, MA (US); **Steve Tallarida**, Mansfield, MA (US)

(21) Appl. No.: **15/591,780**

(22) Filed: **May 10, 2017**

Related U.S. Application Data

(60) Provisional application No. 62/336,210, filed on May 13, 2016.

Publication Classification

(51) **Int. Cl.**

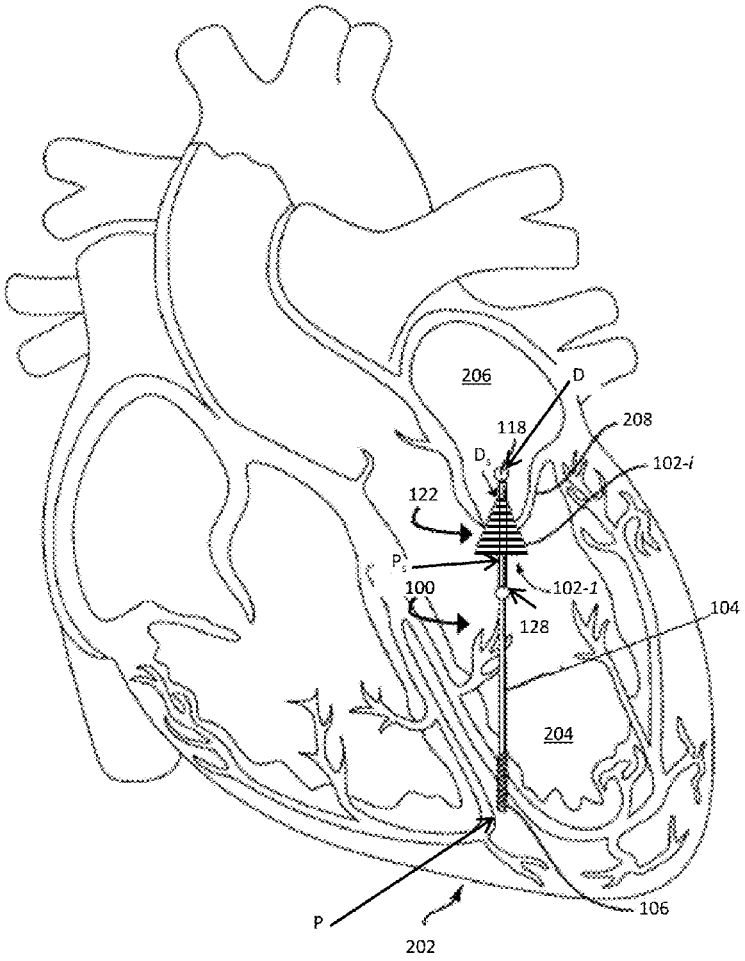
A61F 2/24	(2006.01)
A61F 2/24	(2006.01)
A61L 27/50	(2006.01)
A61L 27/14	(2006.01)
A61L 27/06	(2006.01)
A61F 2/24	(2006.01)
A61F 2/24	(2006.01)
A61F 2/24	(2006.01)

(52) **U.S. Cl.**

CPC ***A61F 2/2421*** (2013.01); ***A61F 2/2436*** (2013.01); ***A61F 2/2457*** (2013.01); ***A61F 2/2487*** (2013.01); ***A61L 27/14*** (2013.01); ***A61L 27/06*** (2013.01); ***A61F 2/2403*** (2013.01); ***A61L 27/50*** (2013.01); *A61F 2210/0014* (2013.01); *A61L 2400/16* (2013.01); *A61L 2430/20* (2013.01); *A61F 2220/0016* (2013.01)

(57) **ABSTRACT**

Heart valve implants and methods for implanting and delivering same are described. A heart valve implant can include a shaft, having a first end and a second end, an anchor, and a plurality of wafers. The anchor is coupled to the first end of the shaft and configured to secure the heart implant to a patient's heart. The wafers are coupled to the second end of the shaft and configured to form a stacked array of wafers. The stacked array of wafers can partially reduce a flow of blood through a heart valve upon coming in contact with a portion of a leaflet of the heart valve.



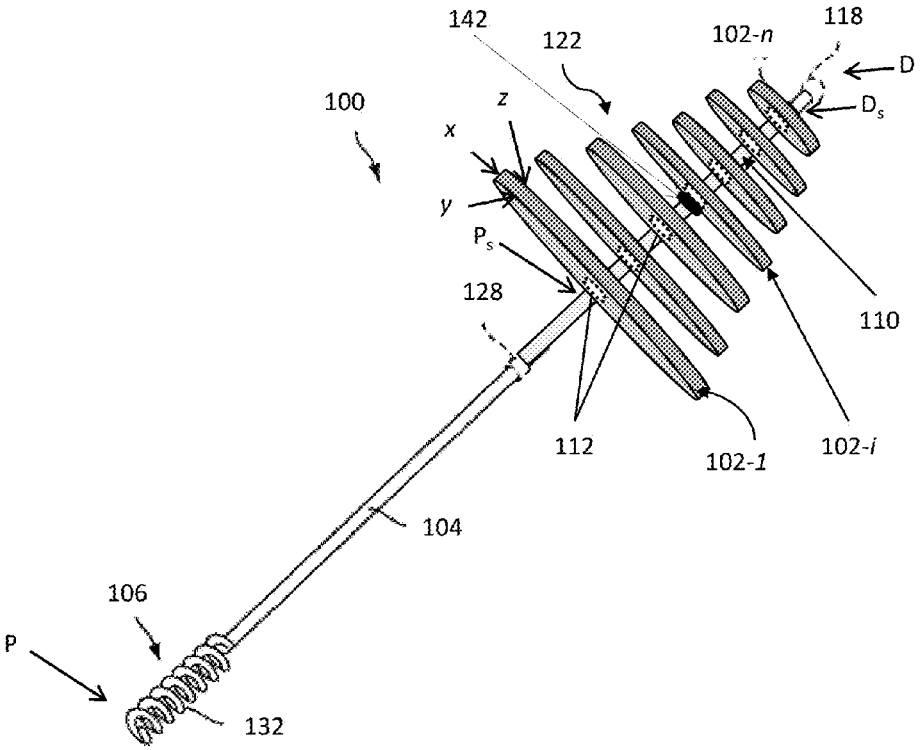

142
122
102-n
118
D
D_s
100
z
x
y
P_s
128
110
112
102-1
102-i
104
106
P
132

FIG. 1

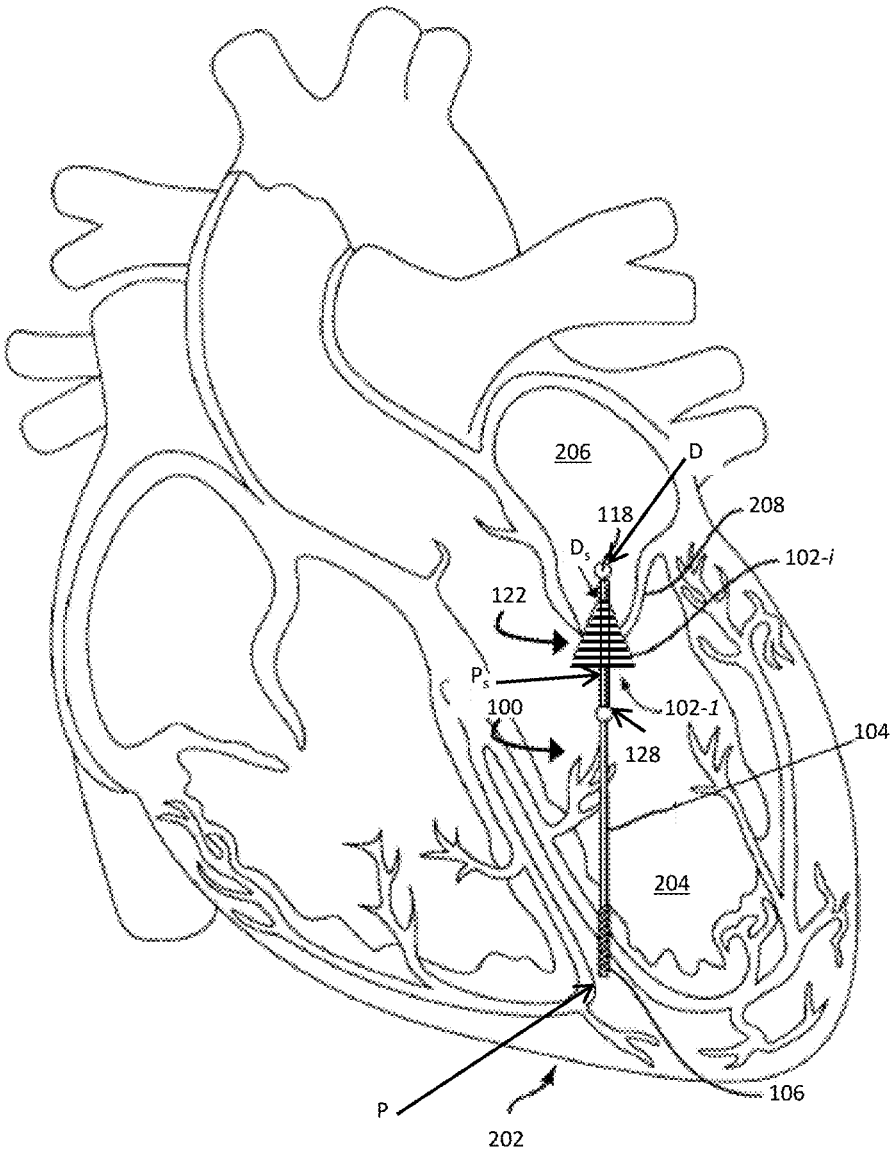


FIG. 2

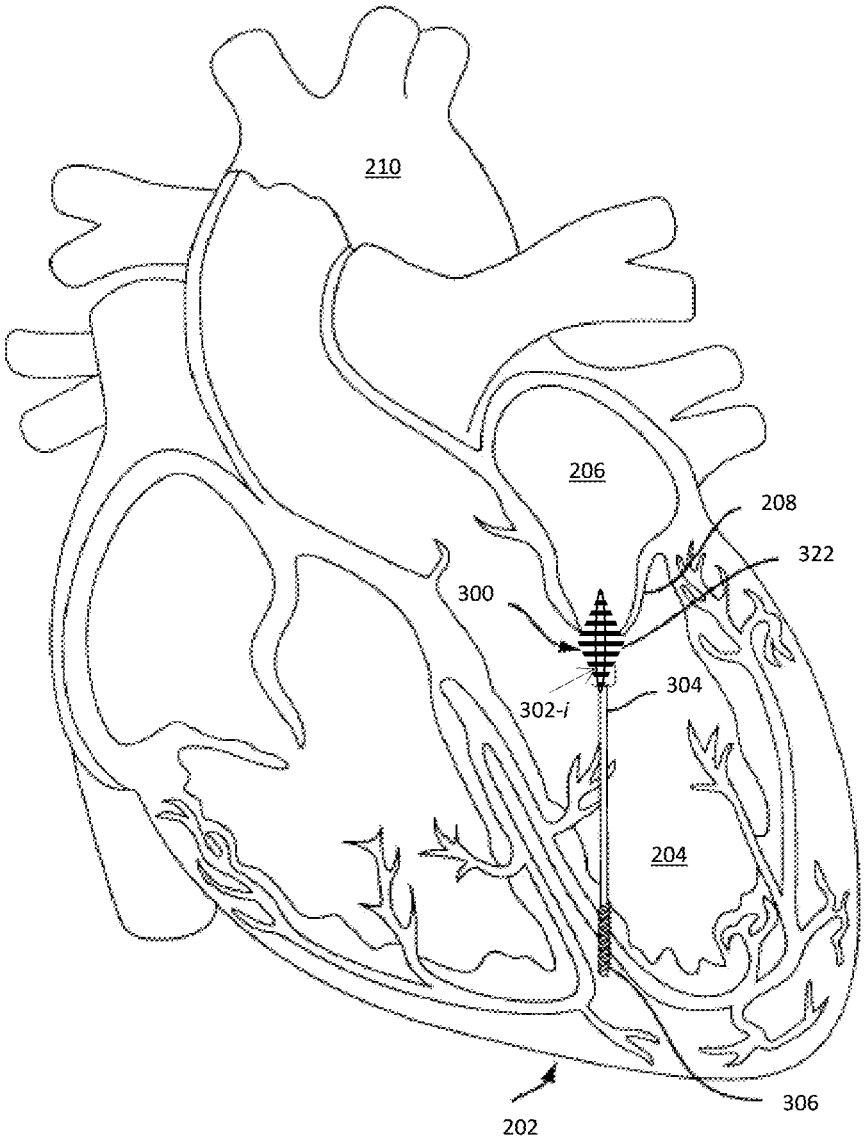


FIG. 3

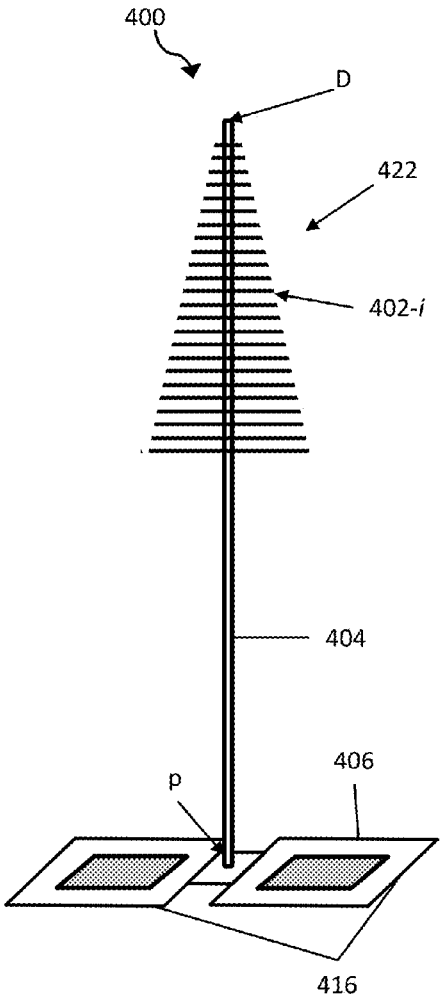


FIG. 4A

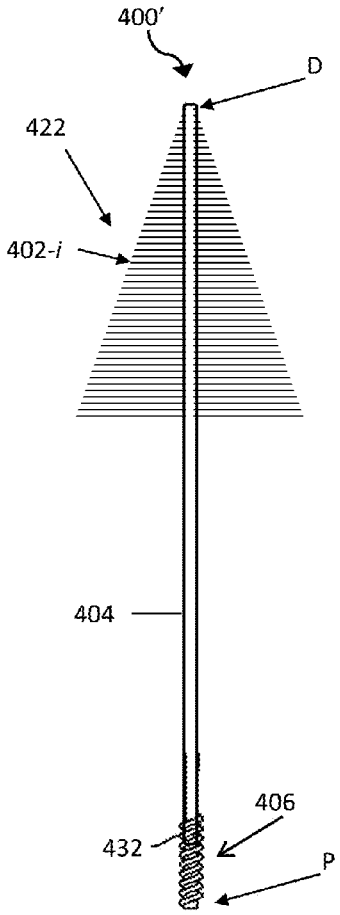


FIG. 4B

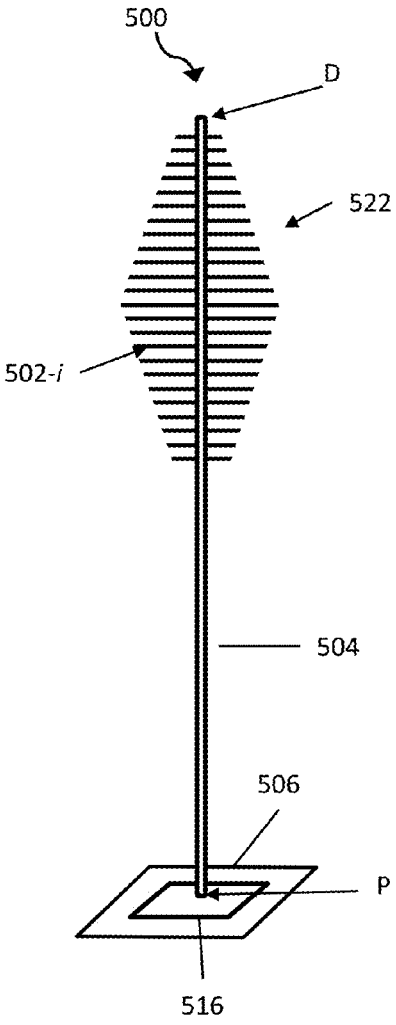


FIG. 5A

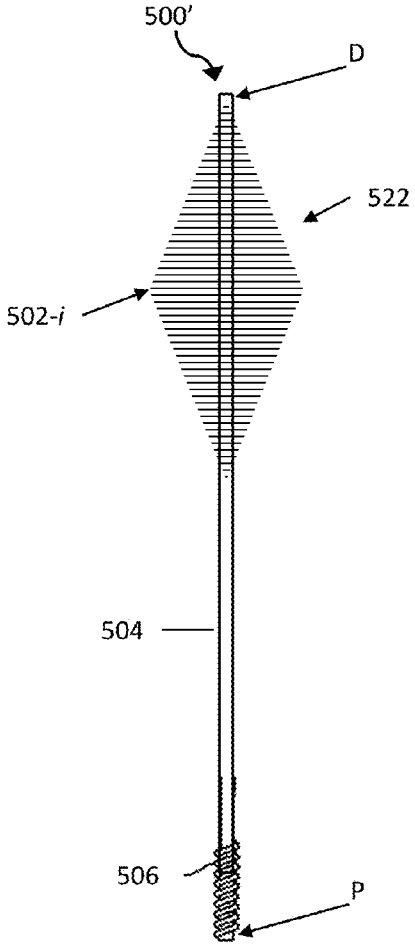


FIG. 5B

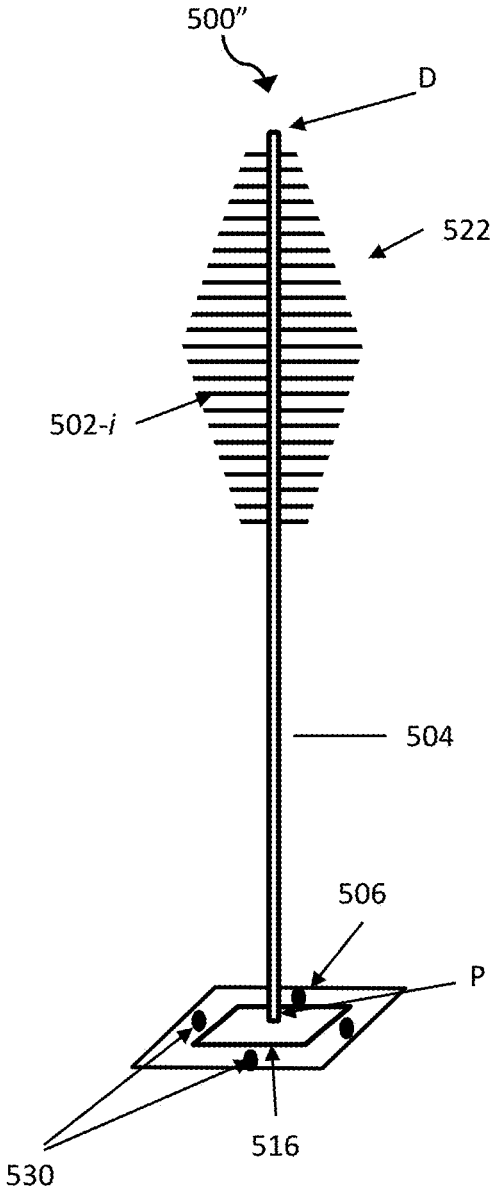


FIG. 5C

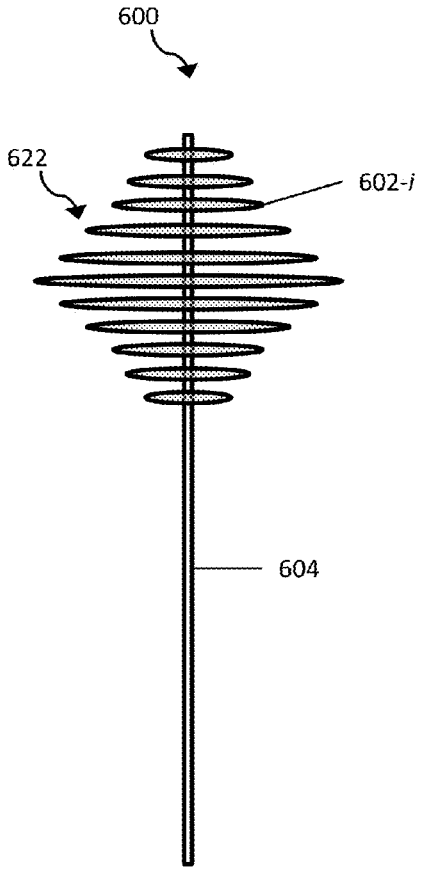


FIG. 6A

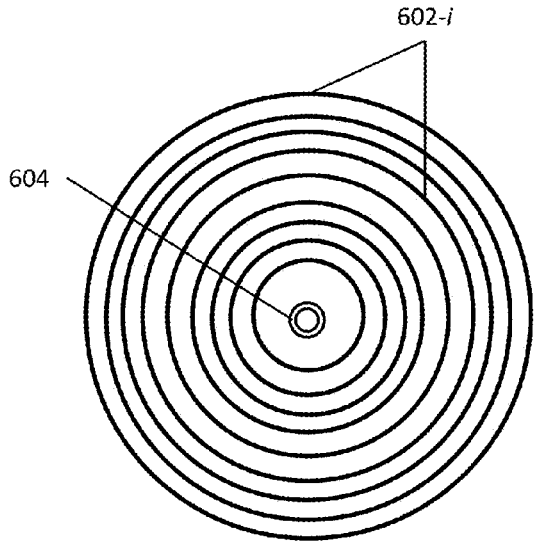


FIG. 6B

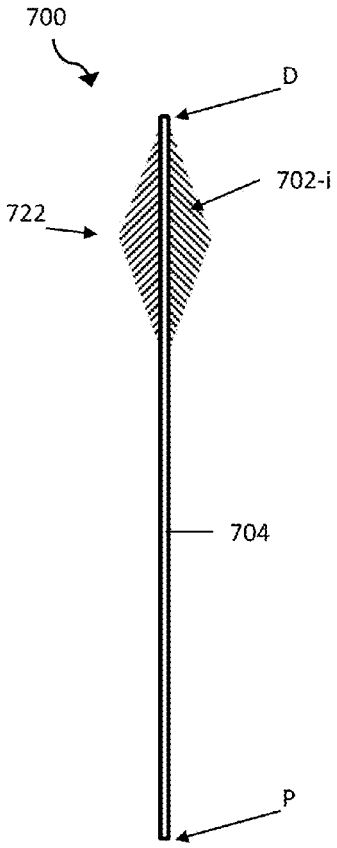


FIG. 7A

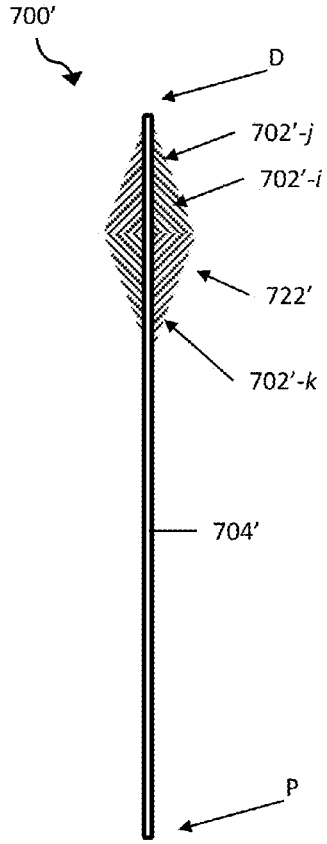


FIG. 7B

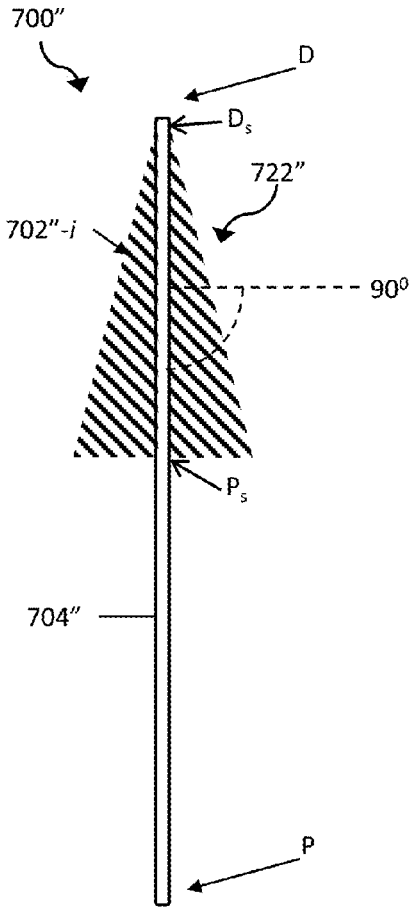

700″
D
D_s
722″
702″-i
90⁰
P_s
704″
P

FIG. 7C

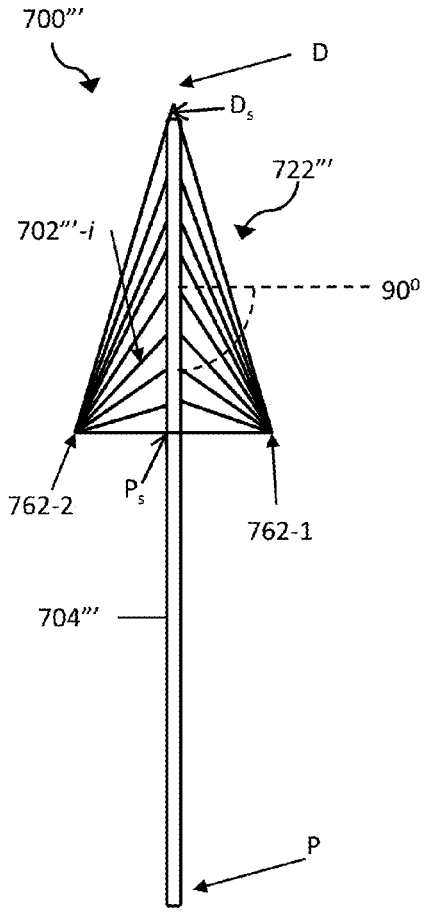

700‴
D
D_s
722‴
702‴-i
90⁰
762-2
P_s
762-1
704‴
P

FIG. 7D

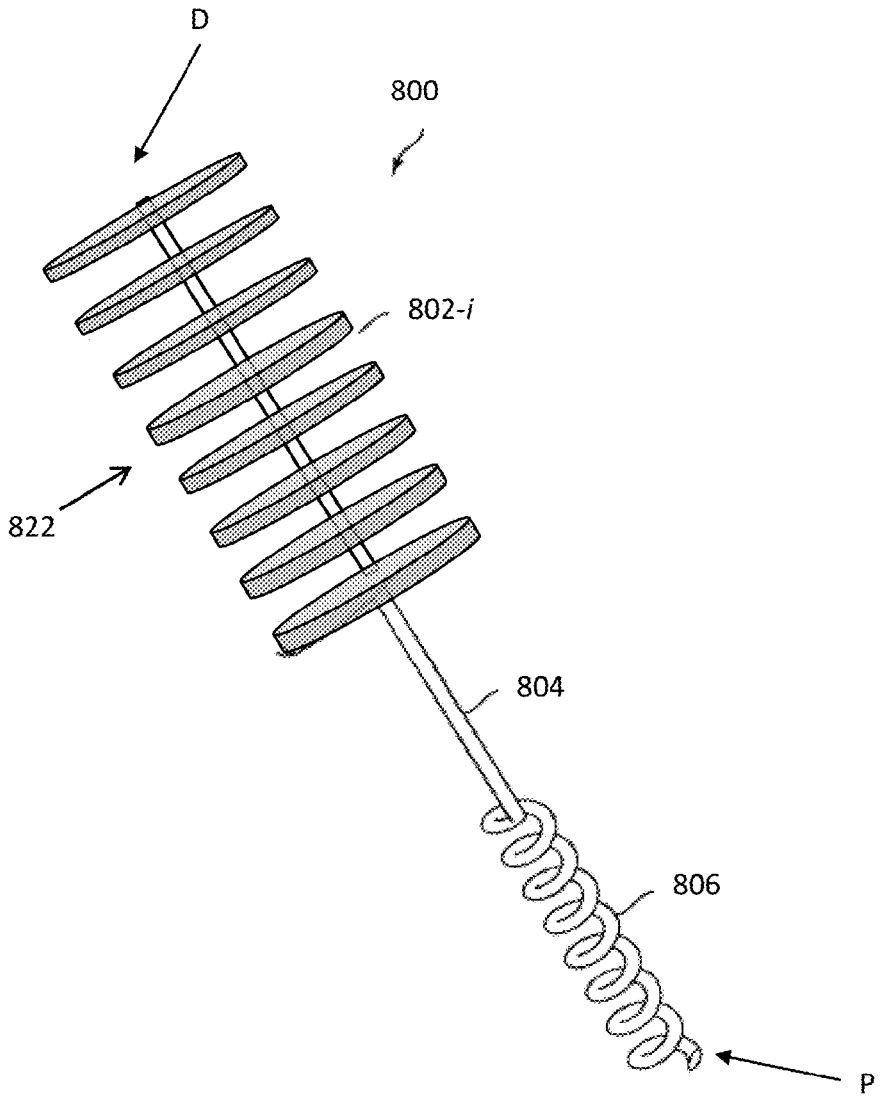


FIG. 8

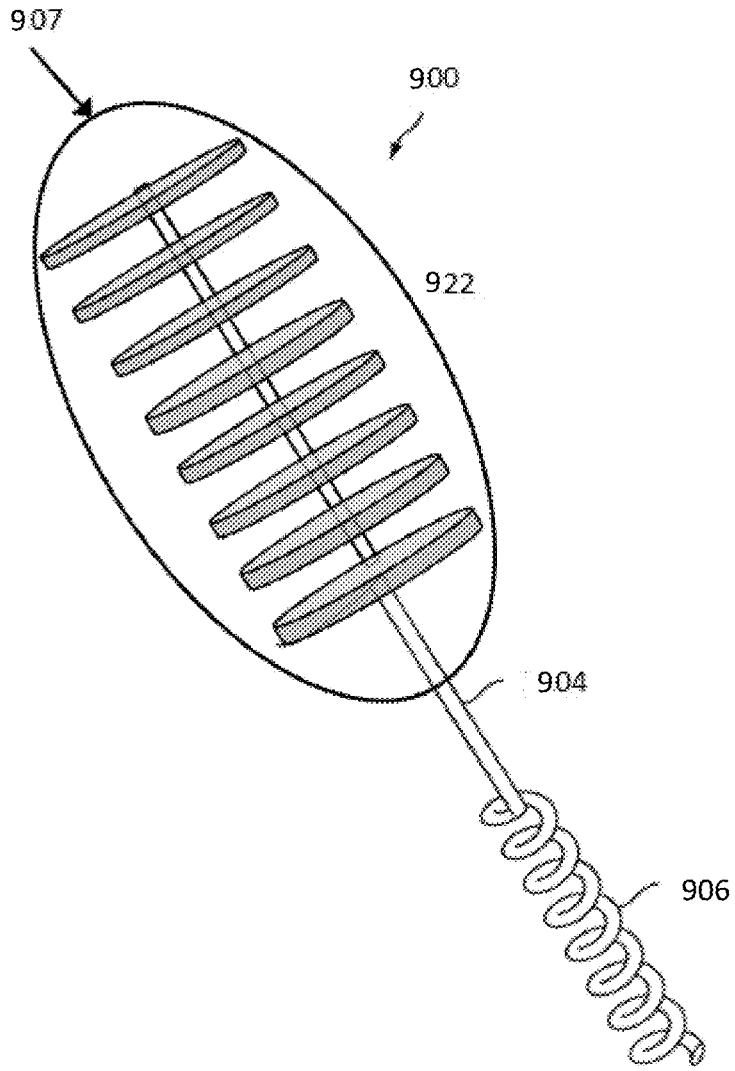


FIG. 9A

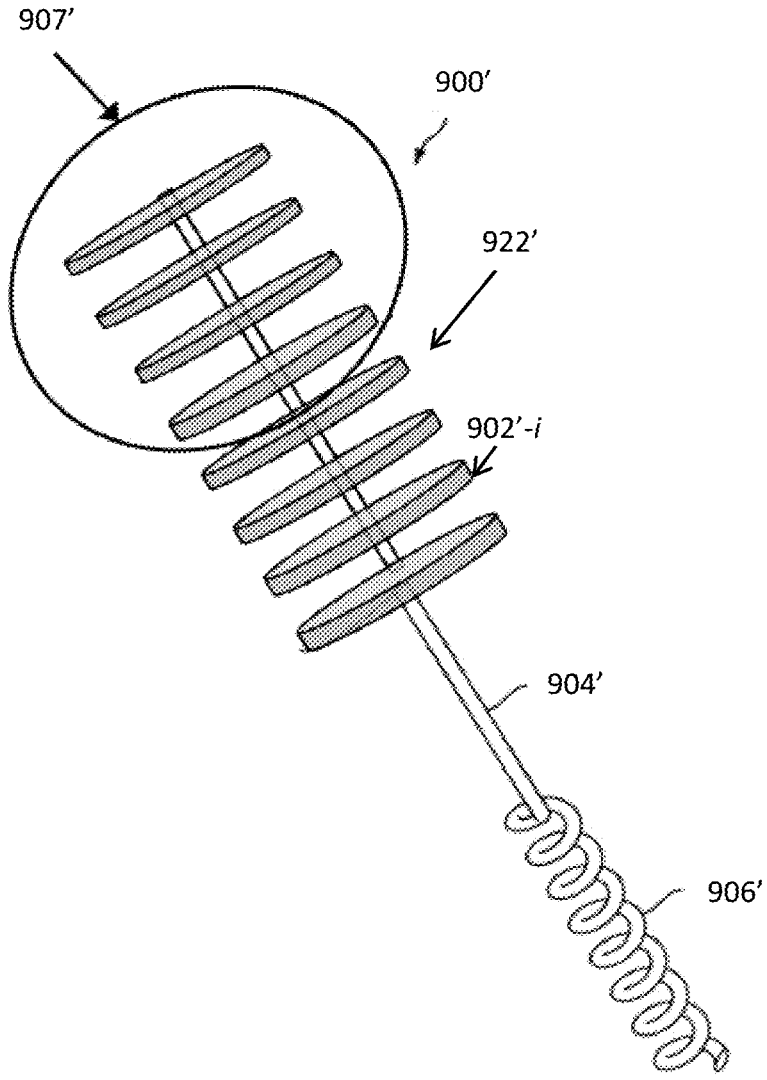


FIG. 9B

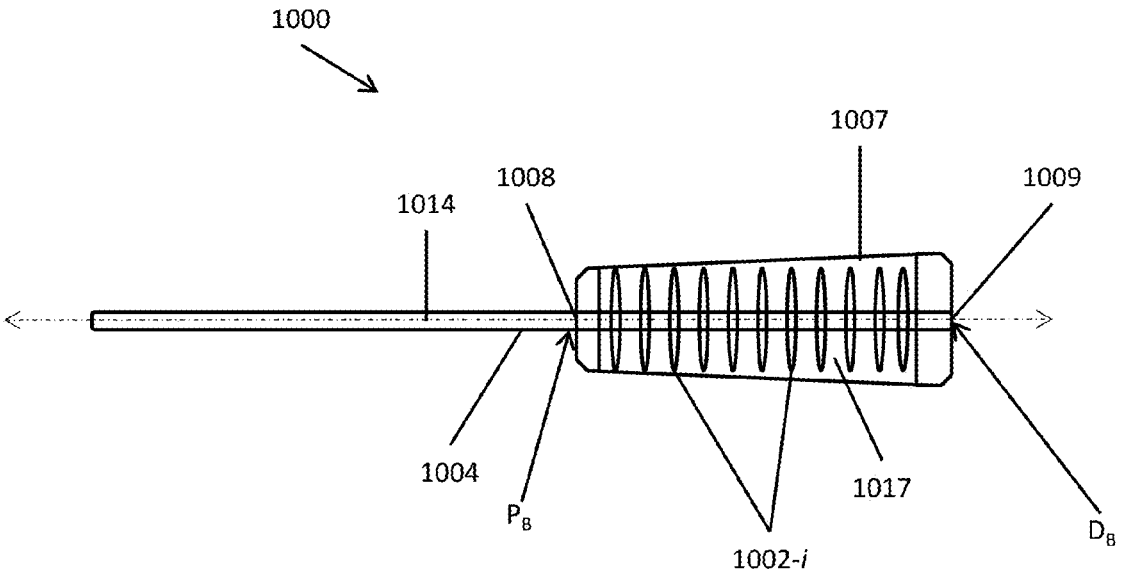


FIG. 10A

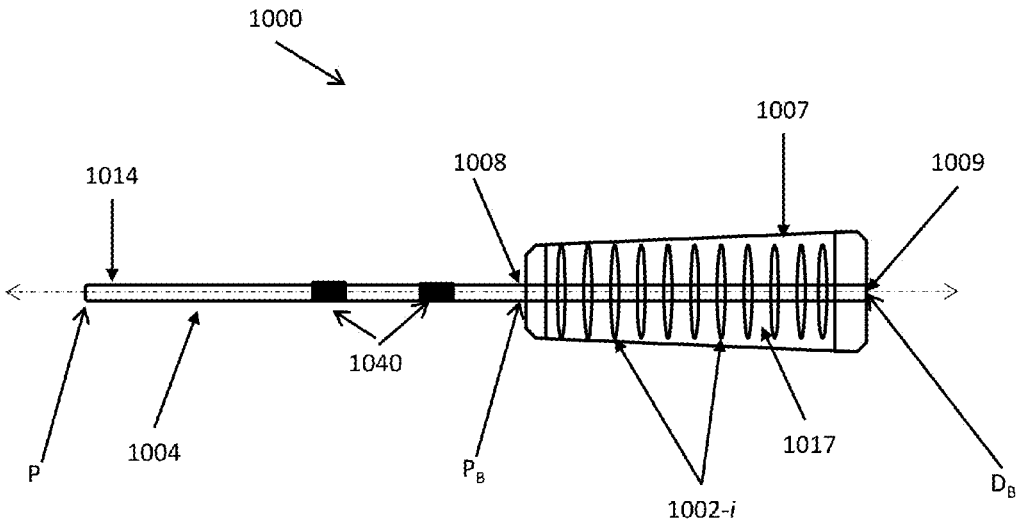


FIG. 10B

HEART VALVE IMPLANT AND METHODS FOR DELIVERING AND IMPLANTING SAME

RELATED APPLICATIONS

[0001] This application claims the benefit of and priority to U.S. Provisional Application 62/336,210, filed on May 13, 2016, the entire teachings of which are incorporated by reference herein.

TECHNICAL FIELD

[0002] The present disclosure relates generally to the repair and/or correction of dysfunctional heart valves, and more particularly to heart valve implants, systems, and methods for delivery and implantation of such implants.

BACKGROUND

[0003] A human heart has four chambers, including the left and right atriums and the left and right ventricles. The chambers of the heart alternately expand and contract to pump blood through the vessels of the body. The cycle of the heart includes the simultaneous contraction of the left and right atria, passing blood from the atria to the left and right ventricles. The left and right ventricles then simultaneously contract, forcing blood from the heart and through the vessels of the body. In addition to the four chambers, the heart also includes a check valve at the upstream end of each chamber to ensure that blood flows in the correct direction through the body as the heart chambers expand and contract. These valves can become damaged or otherwise fail to function properly, resulting in their inability to properly close when the downstream chamber contracts. Failure of the valves to properly close can allow blood to flow backward through the valve, resulting in decreased blood flow and lower blood pressure.

[0004] Mitral regurgitation is a common variety of heart valve dysfunction or insufficiency. Mitral regurgitation occurs when the mitral valve separating the left coronary atrium and the left ventricle fails to close properly. As a result, upon contraction of the left ventricle, blood can leak or flow from the left ventricle back into the left atrium, rather than being forced through the aorta. Any disorder that weakens or damages the mitral valve can prevent the mitral valve from closing properly, thereby causing leakage or regurgitation. Mitral regurgitation is considered to be chronic when the condition persists rather than occurring for only a short period of time.

[0005] Regardless of the cause, mitral regurgitation can result in a decrease in blood flow through the body (e.g., reduce cardiac output). Correction of mitral regurgitation typically requires surgical intervention. Surgical valve repair or replacement can be carried out as an open-heart procedure. The repair or replacement surgery can last in the range of about three to five hours, and can be carried out with the patient under general anesthesia. The nature of the surgical procedure requires the patient to be placed on a heart-lung machine. Because of the severity, complexity, and/or danger associated with open-heart surgical procedures, corrective surgery for mitral regurgitation cannot be recommended in certain patients.

SUMMARY

[0006] Heart valve devices and methods of implanting the same are described herein. In one aspect, a heart valve implant is described. The heart valve can comprise a shaft, having a first end and a second end, an anchor, coupled to the first end of the shaft and configured to secure the heart valve implant to a patient's heart, and a plurality of wafers, wherein each of the plurality of wafers is coupled to the second end of the shaft to form a stacked array of wafers.

[0007] In another aspect, a method for delivering or implanting a heart valve implant is described. The described method comprises: percutaneously inserting the heart valve implant in a patient's heart, wherein the heart valve implant comprises a shaft having a first end and a second end, an anchor coupled to said first end of said shaft, the anchor configured to secure the heart valve implant; and a plurality of wafers, wherein each of the plurality of wafers is coupled to the second end of the shaft. The implanting step comprises at least partially collapsing the plurality of wafers of said heart valve implant, percutaneously inserting said heart valve implant into the heart, securing said anchor of said heart valve implant to native coronary tissue of the said heart (e.g., within the native coronary tissue, within the left ventricle, etc.); and expanding the plurality of wafers to form a stacked array of wafers at least partially within a heart valve to at least partially restrict a flow of blood through a heart valve during systole upon contact with at least a portion of a valve leaflet of the heart valve.

[0008] In yet another aspect, a method for delivering a heart valve implant is described. The described method includes percutaneously inserting a heart valve implant into a patient's heart, wherein the heart valve implant comprises a shaft extending from a first end to a second end, an anchor coupled to the first end of the shaft, and a plurality of wafers coupled to the shaft in proximity of the second end of the shaft, and wherein said wafers are in an at least partially collapsed state. The described method further includes securing said anchor of the heart valve implant to native coronary tissue and expanding the plurality of wafers to form a stacked array of wafers disposed at least partially within the heart valve so as to at least partially restrict a flow of blood through the heart valve during systole.

[0009] In other examples, any of the aspects above, or any system, method, apparatus described herein can include one or more of the following features.

[0010] The stacked array of wafers can be configured to at least partially restrict a flow of blood through the heart valve during systole upon contact with at least a portion of a valve leaflet of the heart valve. The stacked array of wafers can comprise a compliant surface.

[0011] The heart valve implant can further comprise an inflatable balloon. The balloon can surround at least a portion of the plurality of wafers. The balloon can be at least partially inflated with a fluid.

[0012] In some embodiments, the plurality of wafers, by way of example, can comprise a biocompatible polymer, a shape memory material, or a combination thereof. The biocompatible polymer can comprise polyurethane, a polyethylene terephthalate (PET) and polyethyleneoxide (PEO) block copolymer, a polystyrene and poly(1,4-butadiene) block copolymer, a triblock copolymer made from poly(2-methyl-2-oxazoline) and polytetrahydrofuran, a polysiloxane, a polyether, or a combination thereof. In some embodiments, the shape memory material can comprise nitinol.

[0013] The stacked array can comprise a distal end and a proximal end. The stacked array of wafers can exhibit a tapered shape extending from a proximal end to a distal end. The stacked array of wafers can exhibit a diamond-like shape or cross-section. The cross-sectional shape of the stacked array of wafers can include at least one of round, pear-shaped, elliptical, hour-glass shaped, triangular and heart shaped.

[0014] In some embodiments, the plurality of wafers can have substantially equal cross-sectional diameters. The cross-sectional shape of the stacked array of wafers can include at least one of rectangle or square shape.

[0015] The plurality of wafers can be slidably coupled to the shaft. Alternatively or additionally, the plurality of wafers can be fixedly coupled to the shaft. The heart valve implant can further comprise a plurality of coupling members. Each of the plurality of coupling members can be configured to couple at least one of the wafers to the shaft.

[0016] The plurality of wafers can be surrounded all or in part with an outer body or covering (such as a balloon). Such covering can be connected to or separate from the wafers. Such a balloon can be partly filled with fluid.

[0017] Each of the plurality of wafers can include holes, cut-out sections, and/or hollow areas within their body. The wafers can be interconnected at their attachment to the shaft or at locations along the surfaces between the wafers. Such interconnections can comprise one or more materials used in the body of the wafers or of other materials.

[0018] The heart valve implant can comprise one or more radiopaque markers. The one or more radiopaque markers can be disposed on the shaft, one or more of the plurality of wafers, or a combination thereof.

[0019] The anchor of the heart valve implant can comprise at least one barb, a helical feature, at least one anchor pad, or a combination thereof.

[0020] In some embodiments, the heart valve implant can be percutaneously inserted using a catheter. For example, the plurality of wafers can be collapsed and inserted into a lumen of the catheter and the heart valve implant can be delivered to a ventricle (e.g., left ventricle) via said catheter.

[0021] The heart valve implant can be secured to any of an interior surface of the heart, an exterior surface of the heart, or a combination thereof. In some embodiments, the heart valve implant can be a mitral valve implant.

[0022] Other aspects and advantages of the invention can become apparent from the following drawings and description, all of which illustrate the principles of the invention, by way of example only.

BRIEF DESCRIPTION OF THE DRAWINGS

[0023] Features and advantages of the invention described herein, together with further advantages, may be better understood by referring to the following description taken in conjunction with the accompanying drawings. The drawings are not necessarily to scale, emphasis instead is generally placed upon illustrating the principles of the invention

[0024] FIG. **1** is a perspective view of an embodiment of a heart valve implant according to some embodiments disclosed herein.

[0025] FIG. **2** depicts an embodiment of a mitral valve implant consistent with the present disclosure implanted within a heart in a closed position.

[0026] FIG. **3** depicts an embodiment of a mitral valve implant implanted within a heart.

[0027] FIGS. **4**A-**4**B are cross-sectional views of other embodiments having a plurality of wafers consistent with the present disclosure.

[0028] FIGS. **5**A, **5**B, and **5**C are cross-sectional views of other embodiments having a plurality of wafers consistent with the present disclosure.

[0029] FIG. **6**A is a perspective view of an embodiment of a heart valve implant.

[0030] FIG. **6**B is a top view of the heart valve implant of FIG. **6**A.

[0031] FIGS. **7**A-**7**D are cross-sectional views of other embodiments of implants having a plurality of wafers consistent with the present disclosure.

[0032] FIG. **8** is a perspective view of an embodiment of a mitral valve implant shown in an expanded position.

[0033] FIGS. **9**A-**9**B are cross-sectional views of an embodiment of a mitral valve implant that includes a balloon surrounding the wafers.

[0034] FIG. **10**A is a cross-sectional view of another embodiment of a heart valve implant having a balloon that surrounds a plurality of wafers consistent with the present disclosure.

[0035] FIG. **10**B illustrates a heart valve implant having one or more radiopaque markers.

DETAILED DESCRIPTION

[0036] Heart implants and methods and systems for implanting and delivering the implants are described. The heart valve implants described herein can be used in connection with the treatment and/or correction of a dysfunctional or inoperative heart valves. For example, the heart valve implant described herein can be used for treatment and/or correction of mitral valve regurgitation.

[0037] Although implementations of the embodiments described herein can be used for correction and/or treatment of various heart valve (e.g., mitral, aortic, pulmonary, tricuspid) conditions, diseases, or malfunctions, for the ease of explanation, the heart valve implants herein are described in terms of mitral valve implants and in relation to the treatment of mitral valve regurgitation. However, a heart valve implant according to the embodiments of the present disclosure can be configured for treating, use in, and/or correcting other dysfunctional or inoperative heart valves. The present disclosure should not, therefore, be construed as being limited to use as a mitral valve implant and/or for treatment of mitral valve malfunctions.

[0038] Generally, a heart valve implant according to the present disclosure can interact with at least a portion of an existing damaged heart valve to correct the heart valve's dysfunction, e.g., to prevent and/or reduce regurgitation. For example, at least a portion of one or more cusps of the heart valve can interact with, engage, and/or seal against at least a portion of the heart valve implant when the heart valve is in a closed position. By way of example, the interaction, engagement and/or sealing between at least a portion of at least one cusp of a valve (e.g., a mitral valve) and at least a portion of the heart valve implant can reduce and/or eliminate regurgitation in the heart valve. For example, a heart valve may not be able to provide sufficient sealing upon closure due to a variety of different defects, including damage to a single cusp of the valve or removal of a diseased and/or damaged cusp, or a ruptured cordae. A heart valve

implant according to the present disclosure can be used in connection with these and/or alternative, or additional, defects and/or deficiencies.

[0039] Referring to FIG. **1**, a perspective view of an embodiment of a mitral valve implant **100** according to an embodiment of the present teachings is depicted. In general, the mitral valve implant **100** can increase the sealing and/or closure of the passage between the left ventricle and the left atrium during contraction of the left ventricle relative to damaged and/or leaking native valve. Accordingly, in some embodiments the mitral valve implant **100** can be configured to operate in combination with a partially operable and/or damaged mitral valve. That is, the mitral valve implant can interact and/or cooperate with at least a portion of the native mitral valve to reduce and/or eliminate regurgitation.

[0040] As shown, the mitral valve implant can generally include a plurality of wafers **102**-*i*, where i=1, 2, . . . , n, and n∈N. In some embodiments, the number of the wafers can be in average 1 to about 100. The plurality of wafers can form a stacked array of wafers **122**, which are coupled to a portion of the second end (e.g., distal end, D) of a shaft **104**. The first end (e.g., proximal end, P) of the shaft **104** can be coupled to an anchor portion **106**. The anchor portion **106** can be configured to secure the implant to a patient's heart (not shown, see, e.g., FIG. **2**).

[0041] The implant **100** can further include one or more coupling members **142** that are couple at least one of the wafers **102**-*i* to the shaft **104**. For example, as shown in FIG. **1**, a coupling member **142** can couple a wafer **102**-*i* to the shaft **104**. Each of the wafers **102**-*i* can be fixedly or slidably attached to the shaft **104**.

[0042] As noted, the wafers **102**-*i* of the mitral valve implant **100** can form a stacked array of wafers **1622**. The stacked array of wafers can have a tapered profile. The tapered profile can be characterized by a decrease in the cross-sectional area of the wafers **102**-*i* from a proximal end (P_s) to a distal end (D_s) of the stacked array **122**.

[0043] For example, in the embodiment shown in FIG. **1**, each wafer **102**-*i* is in the form of a disc circumscribed by a lateral side (x), a top side (z), and a bottom side (y). The cross-sectional area of the disks decreases from a first disk/wafer **102-1**, positioned at the proximal end (P_s) of the wafer array, to a last disk/wafer **102**-*n*, positioned at the distal end (D_s) of the wafer array **122**.

[0044] The rate of the change in the cross-sectional areas of the wafers **102** can be linear or non-linear. For example, a non-linear change in the cross-sectional areas of the wafers from the first wafer **102-1** to the last wafer **102**-*n* can result in a taper having a flared or billed shape, leading, e.g., to an at least partially concave taper profile. In some embodiments, the wafers **102**-*i* included in the stacked array of wafers **122** can be substantially uniform in size, and, form a generally straight profile once stacked (see, e.g., FIG. **8**). Alternatively and/or additionally, the stacked array of wafers **122** can exhibit a convex profile, producing an at least partially outwardly bulging tapered profile.

[0045] In the example illustrated in FIG. **1**, the wafers **102**-*i* have a substantially uniform thickness. Further, the axial separations **110**, between consecutive wafers, can be substantially uniform. In other implementations, two or more of the wafers can have different thicknesses. Additionally/alternatively, the axial separations **110** between consecutive wafers can be non-uniform. Generally, the spacing **110** between the wafers **102**-*i* and/or the thickness of the wafers **102**-*i* can be uniform or non-uniform.

[0046] Further, the surface of each wafer **102**-*i* can be smooth, non-smooth, or a compliant surface (e.g., the wafer has the ability to change upon application of a force or pressure), to allow for non-turbulent flow of blood over each wafer. Additionally and/or alternatively, the wafers can vary in size, causing the stacked array of wafers **122** to have other shapes than the tapered shape depicted in the example shown in FIG. **1**.

[0047] The wafers **102**-*i* can be slidably coupled to the shaft **104**. Each wafer **102**-*i* can include an opening **112** that allows the wafer to be received by and advanced over shaft **1604**. In some embodiments, the shaft **104** can extend through opening **1612** of the wafers **102**-I to form a stacked array. The opening **112** can be sized to slidably receive at least a portion of the shaft **104** therethrough.

[0048] The shaft **104** can include one or more stops **118** or **128**. The stops **118** and **128** can be sized and/or shaped to control and/or restrict translation of the wafers **102**-*i* along the shaft **104** beyond the stops **118** and **128**. In this manner, as illustrated in FIG. **1**, translation of the wafers **102**-*i* along the shaft **104** can be restricted to the expanse of the shaft **104** between the stops **118** and **128**. In some other embodiments, the wafers **102**-*i* can be fixedly attached to the shaft **104**.

[0049] The stops **118**, **128** can be integrally formed with the shaft **104**. Alternatively, the stops **118**, **128** can be provided as a separate member and coupled to the shaft **104**. In embodiments in which one or more of the stops **118**, **128** are integrally formed with the shaft **104**, the wafers **102**-*i* can be slidably coupled to the shaft **104** by pressing at least one of the stops **118**, **128** through the wafer's opening, which can at least partially elastically deform the opening to permit passage of at least one of the stops **118**, **128** therethrough. Once the one or more of the stops **118**, **128** have been pressed through the opening, the opening can at least partially elastically recover, thereby resisting passage of the one or more stops **118**, **128** back through the opening. Various other arrangements can be employed for providing stops on the shaft and/or for controlling and/or limiting translation of the wafers along the shaft.

[0050] The anchor **106** can include a helical member **132** coupled to the shaft **104**. As shown in FIG. **1**, the helical member **132** can be loosely wound such that adjacent turns of the helical member **132** do not contact one another. For example, the helical member **132** can resemble a corkscrew-type configuration. The anchor portion **106** can be engaged with tissue by rotating the anchor **106** about the axis of the helical member, thereby advancing the anchor **106** into tissue. Consistent with such an embodiment, the anchor **106** can resist pulling out from the tissue. The anchor **106** can be provided as an extension of the shaft **104** in the form of a helical configuration. Alternatively and/or additionally, the anchor **106** can be formed as a separate feature and can be coupled to the shaft **104**, e.g., using mechanical fasteners, welding, adhesive, etc.

[0051] According to various alternative embodiments, the anchor portion **106** can include various configurations capable of being coupled to and/or otherwise attached to native coronary tissue. For example, the anchor portion **106** can include one or more prongs adapted to pierce coronary tissue and to, alone or in conjunction with other features, resist removal of the anchor portion from tissue. For

example, the anchor portion **106** can include a plurality of prongs which can engage native coronary tissue.

[0052] Further, the anchor portion can include features, without limitation, which facilitate attachment to the tissue by suturing. Examples of the features that can be used for facilitating suturing can include rings or openings, suture penetrable tabs, etc. (e.g., shown later in FIG. **4**A). Various other anchor portions that can allow attachment or coupling to native coronary tissue can also suitably be employed in connection with a heart implant according to the present teachings.

[0053] Turning to FIG. **2**, the mitral valve implant **100** is shown implanted within a heart **202**. The mitral valve implant **100** can be disposed at least partially within the left ventricle **104** of the heart **102**. As shown, the anchor portion **106** can be engaged with native coronary tissue within and/or adjacent to the left ventricle **204**. The shaft **104**, coupled to the anchor portion **106**, can extend into the left ventricle **204**. The shaft **104** can further extend at least partially within the mitral valve **208**. For example, the shaft **104** can extend at least partially between the cusps of the mitral valve **208**, and can also extend at least partially into the left atrium **206**. The plurality of wafers **102**-*i* forming a stacked array **122** of the mitral valve implant **100** can be positioned at least partially within the left ventricle **204** with the proximal portion P of the implant **100** disposed within the left ventricle **204** and the distal portion D positioned at least partially within and/or pointed towards the left atrium **206**.

[0054] As the left ventricle **204** contracts, the pressure of blood in the left ventricle **204** can increase such that the blood pressure in the left ventricle **204** is greater than the blood pressure in the left atrium **206**. Additionally, as the pressure of the blood in the left ventricle **204** initially increases above the pressure of the blood in the left atrium **206**, blood can begin to flow towards and/or back into the left atrium **206**. The pressure differential and/or initial flow of blood from the left ventricle **204** into the left atrium **206** can act against the stacked array of wafers **122** and can translate the wafers **102**-*i* toward the left atrium **204**. For example, pressurized blood within the left ventricle **204** can act against the bottom (proximal end P_s) of the stacked array of wafers **122** inducing sliding translation of the stacked array of wafers **122** along the shaft **104** toward the left atrium **206**.

[0055] Illustrated in FIG. **2**, the mitral valve implant **100** is shown in a closed position. In the closed position, the stacked array of wafers **122** can be translated toward and/or at least partially into the left atrium **206**. At least a portion of the stacked array **122** can interact with, engage, and/or be positioned adjacent to at least a portion of the mitral valve **208**. For example, at least a portion of at least one cusp of the mitral valve **208** can contact at least a portion of a sidewall of one or more wafers of the stacked array **122**. Engagement between the stacked array **122** and the mitral valve **208** can restrict and/or prevent the flow of blood from the left ventricle **204** back into the left atrium **206**.

[0056] In addition to the translation of the stacked array of wafers **122**, the mitral valve **208** can also at least partially close around the stacked array of wafers **122**, thereby also restricting and/or preventing the flow of blood from the left ventricle **204** to the left atrium **206**. For example, as mentioned above, at least a portion of one or both of the cusps of the mitral valve **208** can contact at least a portion of the wafers **102**-*i*. As the pressure of the blood in the left ventricle **204** increases, the pressure against the proximal end P_s of the stacked array of wafers **122** can increase. This increase in pressure against the bottom P_s of the stacked array can, in turn, increase the engagement between the stacked array **122** and the mitral valve **208**.

[0057] Sliding translation of the stacked array **122** toward the left atrium **206** can at least partially be controlled and/or limited by the stop **118** coupled to the shaft **104**. Additionally, translation of the stacked array of wafers **122** toward the left atrium **206** can be at least partially limited and/or controlled by engagement between the stacked array and the mitral valve **208**. One or both of these restrictions on the translation of the stacked array can, in some embodiments, prevent the stacked array from passing fully into the left atrium **206**. Furthermore, the diameter of the proximal portion P_s of the stacked array **122** can limit and/or restrict the movement of the stacked array **122** into the left atrium **206**. Once the stacked array of wafers **122** has been positioned, the position of the stacked array of wafers **122** on the shaft **104** can be fixed, e.g. by frictional engagement between the stacked array of wafers **122** and the shaft **104** or using other coupling mechanisms.

[0058] Accordingly, the mitral valve implant **100** can be slidably translatable relative to the mitral valve **208** to reduce and/or eliminate regurgitation. Further embodiments of a mitral valve implant having axially translating wafers can be provided including various alternative wafers configurations. For example, in one embodiment a stacked array can be provided generally configured as a plurality of disc-shaped wafers. In the same manner, as illustrated embodiments of FIGS. **4-7** show, the disc-shaped wafers can translate along a shaft between an open position spaced from the mitral valve of the heart and closed position at least partially engaging the mitral valve and/or at least partially obstructing a flow of blood from the left ventricle to the left atrium. Implants employing wafers having various other geometries, such as spherical, oblong, etc., can also be employed. Furthermore, in addition to the slidably translatable stacked array depicted in FIG. **2**, embodiments can be provided in which the stacked array is rotatably and/or pivotally translatable to engage and/or interact with at least a portion of the mitral valve. Further, in some embodiments, one or more of the wafers can be tilted relative to the shaft.

[0059] In the example shown in FIG. **2**, the illustrated mitral valve implant **100** includes a single anchor portion **106** coupled to a proximal end (P) of the shaft **104**. However, a mitral valve implant according to the present disclosure can include more than one anchor portion for securing the mitral valve implant to native coronary tissue. Additional anchor portions can be employed to provide more secure coupling of the valve implant to coronary tissue. Furthermore, more than one anchor portion can be employed to achieve more precise positioning of the valve implant and/or the wafers portion of the valve implant within the heart. For example, a replacement valve can include an anchor portion coupled to the proximal end of the shaft and another anchor portion coupled to the distal end of the shaft. Further, each end of the shaft can be coupled to native coronary tissue. The orientation of the shaft, and thereby the path of translation of the wafers, can be controlled by coupling each end of the shaft to native coronary tissue. Furthermore, the valve

implant can include an anchor portion coupled to one end of the shaft and another anchor portion coupled to the shaft between the ends thereof.

[0060] The mitral valve implants described herein can be produced from a variety of suitable materials. Generally, such materials are biocompatible. Suitable materials can include, without limitation, biocompatible polymers, such as silicone, polyurethane, etc. Various metals can additionally be used in connection with a valve implant, such as titanium, stainless steel, etc. Additionally, biological materials and/or materials which can promote cellular ingrowth can also be used in connection with a valve implant described herein. Furthermore, various combinations of materials can be used herein, e.g., providing composite features and/or portions made from different materials. For example, the shaft can be formed from a biocompatible polymer or metal and the wafers can be formed from a polymeric material. Various additional and/or alternative combinations can also be employed herein.

[0061] FIG. **3** illustrates a mitral valve implant **300** according to the embodiments described herein. The mitral valve implant **300** is shown after it has been implanted within the heart **202**. As shown in FIG. **3**, the mitral valve implant **300** can be positioned such that it extends at least partially into and/or through the mitral valve **208** between the left ventricle **204** and the left atrium **206**. When the pressure of blood in the left atrium **206** is higher than the pressure of blood in the left ventricle **204**, for example during contraction of the left atrium **206**, the mitral valve **208** can be in an open condition/configuration. In the open configuration, blood can flow from the left atrium **206** through the mitral valve **208** and around the stacked array of wafers **322** and into the left atrium **204**.

[0062] The anchor **306** can be engaged in native coronary tissue surrounding and/or defining at least a portion of the left ventricle **204**. The stacked array of wafers **322** can be positioned extending at least partially between the mitral valve **208** by the shaft **304** extending between the anchor **306** and the stacked array of wafers **322**. In related embodiments, the anchor **306** can be engaged in tissue surrounding and/or defining at least a portion of the left atrium. Further, the stacked array of wafers **322** can be positioned extending at least partially between the mitral valve **208**.

[0063] FIG. **3** depicts the mitral valve implant **300** implanted in a heart **102** with the mitral valve **208** in a closed condition. The closed condition of the mitral valve **208** can occur when the pressure of blood in the left ventricle **204** is higher than the pressure of blood in the left atrium **206**. As shown, when the mitral valve **208** is in a closed condition at least a portion of the mitral valve **208** can interact with, engage, and/or seal against the stacked array of wafers **322** of the mitral valve implant **300**. The presence of the mitral valve implant **300** can enhance the closure of the mitral valve **208** so as to provide an adequate seal, to permit ejection of blood from the ventricle **204** through the aorta **210** and prevent and/or reduce mitral regurgitation.

[0064] The stacked array of wafers **322** can be shaped to facilitate the flow of blood from the left atrium **206** to the left ventricle **204** when the mitral valve **208** is open. The stacked array of wafers **322** can have a generally streamlined shape, allowing for the flow of blood around the stacked array of wafers **322**. For example, the stacked array of wafers **322** can have a generally diamond shape. In other embodiments, the stacked array **322** can have a generally cylindrical, prismatic, etc. shape, without limitation.

[0065] The performance of the mitral valve implant **300** for reducing and/or eliminating mitral valve regurgitation can be, at least in part, related to the positioning of stacked array of wafers **322** relative to the mitral valve **208**. In an embodiment consistent with this aspect, the wafers **302-*i*** can be fixed (e.g., non-slidable) on the shaft **304**. The mitral implant can be positioned such that the stacked array of wafers **322** extends at least partially within the mitral valve **208**. The size of the stacked array of wafers **322** allows for variations in size of a patient's heart, such that the position of the stacked array of wafers **322** can accommodate any differences once the anchor **306** is in the heart **202**.

[0066] The illustrated and described embodiments of the mitral valve implant include a stacked array of wafers coupled to a shaft **304**. The shaft **304**, as used herein, can be a rigid or semi-rigid. Alternatively or additionally, the shaft **304** can be a flexible member. The shaft **304** can be formed of a flexible material, such as a polymer, and can be in the form of a wire or filament. In some embodiments, such a flexible shaft **304** can be coupled to at least two anchor portions (see, e.g., FIG. **4**A). For example, the flexible shaft **304** can extend through the openings in the wafers. An anchor can be coupled to the flexible shaft **304** on one or each side of the wafers **302-*i***. For example, the flexible shaft **304** can be used to position the wafers **302-*i*** relative to the mitral valve **208** and can be anchored or otherwise coupled to the left ventricle **204** and/or to the left atrium **206**, on one or both sides of the wafers **302-*i***.

[0067] A mitral valve implant including a flexible shaft can be employed in implementations including those in which the stacked array of wafers **322** can slidably translate along the flexible material of the shaft **304**. In a related embodiment, the wafers **302-*i*** can be non-slidably coupled to the flexible shaft **304**. The flexible shaft **304** can have a length which permits the wafers to move toward and away from the mitral valve.

[0068] A mitral valve implant including a flexible shaft can also suitably be employed with implementations having stationary (non-translatable) wafers. The wafers **302-*i*** can be generally non-slidably coupled to the flexible shaft **304**. The flexible shaft **304** can be coupled to an anchor that engages native coronary tissue, e.g., via the anchor portions (not shown in FIG. **3**, see for example, FIG. **4**A), etc., on one or both sides of the wafers. Coupling the flexible material on either side of the wafers can generally maintain the wafers in a position within and/or relative to the mitral valve **208**.

[0069] The heart valve implants according to the present disclosure can be implanted using a variety of surgical and/or non-surgical procedures and/or minimally invasive surgical procedures. A surgical implantation procedure can include, for example, an open heart procedure in which the implant can be directly placed into the heart and manually positioned relative to the heart valve.

[0070] A heart valve implant consistent with the present disclosure can also advantageously be implanted using less invasive procedures. For example, the heart valve implant can be implanted using a percutaneous procedure. A suitable percutaneous implantation procedure can include a catheterization procedure. For example, if used as a mitral valve implant in a percutaneous catheterization procedure, the mitral valve implant can be delivered to the heart using a catheter inserted into a vein or artery or directly into the

heart itself (via the apex), depending upon the desired delivery site, and into the left atrium or the left ventricle. For example, the mitral valve implant can be delivered via a transceptal approach, in which the catheter is inserted, e.g., via a vein, into the right atrium. The catheter can then pass through a puncture between the right atrium to the left atrium and further through the mitral valve to the left ventricle, if desired. Generally, according to a catheterization procedure, the vein or artery can be accessed through a percutaneous incision or puncture. A catheter carrying the mitral valve implant can be introduced into the vein or artery through the incision or puncture. The catheter and mitral valve implant can be passed through the vein or artery into the heart. Once in the heart, the mitral valve implant can be deployed from the catheter and positioned within and/or between the left ventricle and the left atrium.

[0071] At least a portion of the heart valve implants described herein can be collapsible and/or reducible in volume to facilitate percutaneous and/or transluminal delivery. In such a manner, the wafers of the mitral valve implant can be collapsible, which can be reduced in volume and/or reduced in maximum diameter during delivery to the heart and/or during placement and/or attachment of the anchor to native coronary tissue. After delivery to the heart, the wafers can be expanded, inflated, and/or otherwise increased in volume or size. Accordingly, the mitral valve implant can be delivered to an implantation site via a smaller diameter catheter, and/or via smaller vessels, than would otherwise be required.

[0072] The wafers can be formed from a resiliently deformable material, such as an elastomer, which can be elastically deformed under stress. The wafers can elastically recover when the stress is removed. In such an embodiment, the wafers can, for example, be deformed from an expanded configuration to a collapsed condition and loaded into a catheter delivery system. After delivery to an implant site, the wafers can be deployed from the catheter delivery system, thereby removing the deforming stress from the wafers. Once the deforming stress is removed, the wafers can resiliently recover back to the expanded configuration.

[0073] FIGS. **4**A-**4**B are examples of mitral valve implants **400**, **400'**, according to the embodiments disclosed herein. The example mitral valve implants **400**, **400'** include a shaft **404** having a proximal end (P) and a distal end (D). A plurality of wafers **402**-*i* are disposed or coupled to the shaft **404** at or near the distal end (D) of the shaft **404**. The plurality of wafers **402**-*i* form a stacked array of wafers **422**.

[0074] In FIG. **4**A, the wafers **402**-*i* are stacked substantially parallel to each other and have substantially the same spacing between the wafers **402**-*i*. Wafers **402**-*i* are also coupled to shaft **404** such that they are substantially perpendicular to the shaft. In FIG. **4**B, the wafers **402**-*i* are also stacked substantially parallel to each other and have substantially the same spacing between the wafers **402**-*i*. However, the wafers **402**-*i* are spaced closer together than the wafers **402**-*i* illustrated in FIG. **4**A.

[0075] In the embodiments illustrated in FIGS. **4**A-**4**B, the cross-sectional diameter of each of the wafers **402**-*i* in the stacked array **422** is variable, and the size (e.g., diameter) of each wafer **402**-*i* is different. The stacked array of wafers **422** of FIGS. **4**A and **4**B have a generally triangular shape, with the diameters of the wafers progressively decreasing from a maximum value to a minimum value close to the distal end of the shaft (D). Once implanted in the heart (not shown, see, e.g., FIG. **3**), a portion of the tapered stacked array of wafers **422** can be disposed above the mitral valve in the left atrium. The proximal portion can be disposed below the mitral valve in the left ventricle. The size and shape of each of the wafers **402**, which determines the size and shape of the stacked array **422**, can be configured for placement within the heart valve (e.g., a mitral valve), so as to at least partially restrict blood flow through the heart valve during systole. Various sizes and shapes of wafers **402**-*i* (and, thereby, various sizes and shapes of stacked array of wafers **422**) can be utilized. The size and shape of the wafers **402**-*i* on the heart valve in which the implant is implanted.

[0076] As shown in FIG. **4**B, an anchor **406** can be coupled to the shaft **404** at or near the first end. The anchor **406** can be used to secure the mitral valve implant **400'** to a patient's heart. As noted, the mitral valve implant **400**, **400'** can generally include a plurality of disc-shaped wafers **402**-*i* coupled to a shaft **404**. The wafers **402**-*i* can be coupled to the shaft **404** in a stationary fashion, e.g., the wafers can be coupled to the shaft in a non-slidable manner. Generally, the wafers **402**-*i* can be maintained at a generally fixed position on the shaft **404**. The mitral valve implant **400**, **400'** can be implanted in the heart such that the anchor **406** and the shaft **404** can maintain the wafers **402**-*i* in a desired position relative to various elements/features of the coronary anatomy. According to one aspect, the anchor **406** and the shaft **404** can maintain the wafers **402**-*i* positioned extending at least partially within the mitral valve.

[0077] The wafers **402**-*i* can be maintained in a stationary position on the shaft **404** in various ways. For example, wafers **402**-*i* can be integrally formed on the shaft **404**. Additionally and/or alternatively, the wafers **402**-*i* can be adhesively bonded, welded, staked, and/or mechanically fastened to the shaft **404**. As noted with reference to FIG. **1**, the shaft **404** can include one or more stops or features (not shown in FIG. **4**) which can prevent and/or limit translation of the wafers along the shaft. For example, the shaft **404** can include a stop (not shown in FIG. **4**, see, e.g., FIG. **1**) closely positioned on either end of the stacked array of wafers **422**, thereby restricting movement of the wafers. The stops can be fixed and/or can be adjustable along the shaft **404**. Various other configurations and/or arrangements can be employed for coupling the wafers **402** in a stationary manner with respect to the shaft **404**. For example, as noted on FIG. **1**, one or more coupling members **142** can be used to couple each wafer **102**-*i* to the shaft **142**.

[0078] Any number of anchors known in the art can be used to secure the mitral valve implant **400**, **400'** to the heart, such as barbs, helical members, anchor pads, etc. For example, anchor **406** of FIG. **4**A is coupled to a first end of shaft **404**. The anchor **406** can have one or more anchor pads **416** that can be used to secure the implant **400**, **400'** to a wall of the heart. The anchor pads **416** can allow for tissue ingrowth and/or one or more sutures to secure the anchor to heart tissue. Consistent with related embodiments, the anchor **406** can be formed as a separate feature and can be coupled to the shaft **404**, e.g., using mechanical fasteners, compression fittings, welding, adhesive, etc. The anchor pads **416** can be placed on an inside surface of the heart, an outside surface of the heart, or both. In instances where anchor pads **416** are secured to both an inside and outside surface of the heart, or to an outside surface only, the shaft **404** can extend through a heart wall (e.g., the left ventricle). The anchor pads **416** (e.g., tabs or rings) can provide

suturing features (not shown, see, e.g., FIG. **5**C) through which sutures can pass to secure the anchor to coronary tissue. For example, as shown in FIG. **5**C, the anchor pad **416**, **516** can include a plurality of holes **530** that allow suturing the anchor pad **416**, **516** to the heart tissue.

[0079] In FIG. **4**B, anchor **406** includes a helical member **432** having a corkscrew shape coupled to the shaft **404**. The helical member **432** can be loosely wound such that adjacent turns of the helical member **432** do not contact one another, for example resembling a corkscrew-type configuration. The helical member **432** of the anchor **406** can be engaged with coronary tissue (not shown, see, e.g., FIG. **2**) by rotating the anchor **406** about the axis of the helix **432**, thereby driving the anchor **406** into native coronary tissue. Once the anchor **406** has been engaged with native coronary tissue, the anchor **406** can resist axial pull-out from the tissue. The anchor **406** can be provided as an extension of the shaft **404** wound in a helical configuration. Consistent with related embodiments, the anchor **406** can be formed as a separate feature and can be coupled to the shaft **404**, e.g., using mechanical fasteners, welding, adhesive, etc. The anchor **406** can additionally and/or alternatively be provided having various features and/or configurations.

[0080] FIGS. **5**A-**5**C illustrate example embodiments of the mitral valve implant **500**, **500'**, **500"**. The mitral valve implant **500**, **500'**, **500"** can have a shaft **504** with a proximal end (P) and a distal end (D). An anchor **506** is coupled to the shaft **504** at or near the proximal end (P) thereof and arranged to secure the mitral valve implant **500**, **500'**, **500"** to a patient's heart (not shown, see, e.g., FIG. **2**). A plurality of wafers **502**-*i* are disposed or coupled to the shaft **504** at or near the distal end (D) of the shaft **504**. The plurality of wafers **502**-*i* form a stacked array of wafers **522**.

[0081] In FIG. **5**A, the wafers **502**-*i* are stacked substantially parallel to one another and arranged to have substantially the same spacing between the wafers **502**-*i*.

[0082] In FIG. **5**B, the wafers **502**-*i* are also stacked substantially parallel to each other and have substantially the same spacing between the wafers **502**-*i*, but the wafers are spaced closer together than the wafers illustrated in FIG. **5**A.

[0083] In the embodiments illustrated in FIGS. **5**A-**5**C, the cross-sectional diameter of the stacked array of wafers is variable, i.e., the width (diameter) of each wafer varies. The stacked array of wafers **522** of FIGS. **5**A-**5**C have a generally symmetrical shape, forming a diamond-like shape. The size and shape of each of the wafers **502**-*i*, determines the size and shape of the stacked array **522**. This shape (of the stacked array **522**) is configured for placement within a heart valve (e.g., a mitral valve, not shown, see, e.g., FIG. **2**), so as to restrict blood flow through the heart valve during systole.

[0084] As noted previously, the cross-sectional shape of the stacked array of wafers can be sized for placement within a heart valve, such as a mitral valve or any other heart valve in which the implant may be implanted. The shapes illustrated in FIGS. **5**A-**5**C are provided as examples, and other shapes, for example, round, oval, pear-shaped, elliptical, hour-glass shaped, and heart shaped, can be used in the heart valve implants described herein. These shapes can have a variable cross-sectional diameter, in which the wafers have varying sizes. These shapes can also have a substantially equal cross-sectional diameter, in which the wafers have about equal widths, for example, in rectangular and square shaped arrays.

[0085] The wafers can form a compliant (e.g., a smooth) surface with which heart valve leaflets can engage. For example, the wafers can comprise a biocompatible polymer, a shape memory material, or a combination thereof. Shape memory materials are known in the art and can comprise, for example, an alloy, a polymer, or a combination thereof. Nitinol is an example of a shape memory alloy. Examples of shape memory polymers are polyurethanes, polyurethanes with ionic or mesogenic components made by prepolymer method, block copolymers of polyethylene terephthalate (PET) and polyethyleneoxide (PEO), block copolymers containing polystyrene and poly(1,4-butadiene), and an ABA triblock copolymer made from poly(2-methyl-2-oxazoline) and polytetrahydrofuran. Other polymers, for example, can include polysiloxanes (silicones) and polyethers.

[0086] The wafers can be collapsed and/or otherwise deformed from an expanded configuration. The collapsed and/or deformed wafers can maintain the collapsed and/or deformed configuration after the initial deforming stress is released. The wafers can subsequently be returned to the expanded and/or operable configuration, for example, by heating the wafers above an activation temperature of the shape memory material, which can induce recovery of the shape memory material to a pre-deformed shape. The activation temperature inducing recovery of the deformed wafers can be provided by the body temperature of the patient receiving the mitral valve implant. Alternatively or additionally, heat for activating recovery of the shape memory material can be provided by a heating element coupled to the wafers and/or a heating element delivered through a catheter. Heat activation can also be provided by irradiating the shape memory material using suitable radiation techniques, such as, with microwaves, IR light, etc.

[0087] The wafers can also be collapsed and/or deformed to facilitate delivery of the implant to the desired site, e.g., via a transluminal and/or a surgical procedure. The wafers can subsequently be recovered to an expanded configuration. For example, when using a thermally activated shape memory material, recovery of the shape memory wafers can be accomplished by heating the wafers to, or above, an activation temperature. Heat for activating the shape memory material can be provided by the body temperature of the subject receiving the mitral valve implant, and/or from an external source, e.g., via the catheter, etc.

[0088] Referring back to FIGS. **5**A-**5**C, the wafers can be slidably coupled to the shaft. For example, each wafer can have a central channel (e.g., opening **112**, shown in FIG. **1**) to receive the shaft **504** and advance over the shaft **504**. One or more coupling members (e.g., coupling member **142**, shown in FIG. **1**) can couple each wafer to the shaft **504**. The wafers can coupled directly with the shaft **504**. In some embodiments, the wafers can be attached to the shaft **504** such that they are not slidably attached. For example, as noted above, the wafers can be fixedly attached to the shaft.

[0089] As shown in FIGS. **5**B-**5**C, the anchor **506** of mitral valve implant **502**, **503** can have an anchor pad **516** that can be used to secure the implant **500** to a wall of the heart (not shown, see, e.g., FIG. **2**). The anchor pad **516** can allow for tissue ingrowth and/or one or more sutures **530** to secure the anchor to heart tissue. The anchor pad **516** can be placed on an inside surface of the heart or an outside surface of the heart. In instances where anchor pad **516** is secured to an outside surface, the shaft **504** extends through a heart wall (e.g., the left ventricle). As shown in FIG. **5**C, the anchor pad

516 (e.g., a tab or ring) can provide suturing features **530** through which one or more sutures can pass to secure the anchor **504** to coronary tissue.

[0090] FIG. **6**A is a perspective view of an example heart valve implant **600** according to embodiments disclosed herein. In this example, wafers **602**-*i* have a substantially circular or disc-like shape and are each coupled to shaft **604**. The plurality of wafers **602**-*i* form a stacked array of wafers **622** having two wafers at each end with a minimum diameter and a wafer at the middle with a maximum diameter. The spacing between wafers **602** can be substantially equal, as illustrated in FIG. **6**A, or can vary.

[0091] FIG. **6**B is a top view of the heart valve implant **600** shown in FIG. **6**A. The shaft **604** is disposed generally along a central axis. Wafers **602**-*i* are generally circular in shape and are configured to be sized for at least partial placement in a heart valve.

[0092] FIG. **7**A illustrates a heart valve implant **700** having a plurality of wafers **702**-*i* forming a stacked array **722**. Similar to the stacked array **522** illustrated in FIG. **5**A-**5**C, the cross-sectional shape of the stacked array of wafers **722**, shown in FIG. **7**A, can be diamond-shaped, having two wafers at both ends with a minimum diameter and a wafer in the middle with a maximum diameter. Further, each of the plurality of wafer **702**-*i* can be coupled to a shaft **704** at a non-perpendicular angle (i.e., less than 90°) relative to the shaft **704**. The shaft **704** can have a proximal end (P) and a distal end (D). The wafers **702**-*i* can be configured such that, once implanted, they are directed to or angled towards the proximal end (P) of shaft **704** (e.g., if used as a mitral valve implant, they are angled downwards towards the left ventricle in a "V" shape formation). For example, each one of the wafers **702**-*i* can be angled at any of less than 90°, less than 80°, less than 70°, less than 60°, less than 50°, less than 40°, less than 30°, less than 20°, or less than 10° relative to shaft **704**. When used as a mitral valve implant, in such a configuration, the implant **700** can allow blood to more easily flow from an atrium to a ventricle during diastole. During systole, blood flow is at least partially restricted back through the heart valve because of contact between a portion of a valve leaflet with the stacked array. Also, the angle of and space between each of the wafers **702**-*i* forming the stacked array **722** further prevents valve regurgitation even if valve leaflets do not completely abut against the stacked array **722**.

[0093] In the example shown in FIG. **7**B, the heart valve implant **700'** has a plurality of wafers **702'**-*i* forming a stacked array **722'**. Similar to the stacked array **722** illustrated in FIG. **7**A, the cross-sectional shape of the stacked array of wafers **722'** can be diamond-shaped, having two wafers at both ends with a minimum diameter and a wafer in the middle with a maximum diameter. Each of the wafers **702'**-*i* can be coupled to the shaft **704'** at a non-perpendicular angle relative to shaft **704'**. Wafers **702'**-*i* can be "V" shaped and oriented in opposite directions. Specifically, some of the wafers (e.g., wafer **702'**-*j*) can be configured such that they are directed to or angled towards the proximal end (P) of the shaft **704'**(e.g., angled towards the left ventricle when used as a mitral valve implant). Some of the other wafers (e.g., for example wafer **702'**-*k*) can be configured such that they are directed to or angled towards the distal end (D) of shaft **704'** (i.e., angled towards the left atrium). For example, each one of the wafers **702'**-*i* can be oriented or coupled with shaft **704'** at a non-90 degree angle. Specifically, wafers **702'**-*i* can be angled at more or less than 90°. In some embodiments, the wafers **702'**-*i* are angled at less than 80°, less than 70°, less than 60°, less than 50°, less than 40°, less than 30°, less than 20°, or less than 10° relative to shaft **704'**. In such a configuration, the heart valve implant **700'** (e.g., when used as a mitral valve implant) can allow blood to more easily flow from an atrium to a ventricle during diastole. During systole, blood flow is at least partially restricted back through the heart valve because of contact between a portion of a valve leaflet with the stacked array. Also, the angle of and space between each of the wafers forming the stacked array further prevents valve regurgitation even if valve leaflets do not completely abut against the stacked array.

[0094] Referring to FIG. **7**C, the heart valve implant **700"** is yet another embodiment of the heart valve implant disclosed herein. The mitral valve implant **700"** can have a plurality of wafers **702"**-*i* at a non-perpendicular angle relative to the shaft **704"** forming a stacked array of wafers **722"**. The cross-sectional shape of stacked array can be triangular or tree-shaped. Similar to FIG. **7**A, wafers **702"**-*i* are coupled to the shaft **704"** such that they are directed to or angled towards the proximal end (P) of the shaft **704"**, (e.g., angled downwards towards the proximal end (P)). For reference, a right angle is illustrated with dotted lines in FIG. **7**C. The stacked array of wafers **722"** has a distal portion (D_s) that is configured to at least partially sit above a heart valve (e.g., in a left atrium) and an proximal portion (P_s) that is configured to at least partially sit below a heart valve (e.g., in a left ventricle).

[0095] The wafers **702**-*i* and wafers **702"**-*i* shown in FIG. **7**A and FIG. **7**C are arranged such that each wafer **702**-*i*, **702"**-*i* is coupled to the shaft **704**, **704"** at approximately the same angle (e.g., an angle less than 90°). However, in some embodiments, a heart valve implant can have a plurality of wafers that are each coupled to a shaft at a range of angles, for example, between 0 and 180° (e.g., FIG. **7**B). For example, the plurality of wafers forming a stacked array can be coupled to the shaft from about 10° to about 90°, from about 20° to about 90°, from about 30° to about 90°, from about 40° to about 90°, from about 20° to about 80°, from about 30° to about 70°, or from about 40° to about 60° relative to the shaft.

[0096] FIG. **7**D illustrates another embodiment of the heart valve implant **700'"**. The implant **700'"** includes a plurality of wafers, each of which 702'"-*i* varies in size and angle at which the wafer **702'"**-*i* is coupled to the shaft **704'"**. The plurality of wafers **702'"**-*i* form a stacked array **722"**. The cross-sectional shape of stacked array **722'"** can be triangular or tree-shaped. The stacked array of wafers **722'"** has a distal portion (D_s) that is configured to at least partially sit above a heart valve (e.g., in a left atrium) and a proximal portion (P_s) that is configured to at least partially sit below a heart valve (e.g., in a left ventricle). The angle at which each wafer **702'"**-*i* is coupled to the shaft **704'"** gradually increases from the distal end to the proximal end. The wafers at the tapered/distal end (D_s) of the stacked array of wafers **722'"** have a non-zero angle of coupling, which increases to about 90 degrees at the enlarged/proximal end (P_s) of the stacked array of wafers **722"**. Also, the size of each wafer **702'"**-*i* gradually decreases from the distal end (D_s) of the stacked array of wafers **722'"** to the proximal end (P_s) of the stacked array of wafers **722"**.

[0097] In the example shown in FIG. **7**D, each wafer **702'"**-*i* is generally directed towards the proximal end (P_s) of

stacked array of wafers **722"**, and ends at or near the enlarged ends/the proximal end (P_s) of the stacked array of wafers **722"**. Each of the plurality of wafers **702'"-***i* can be coupled together on the proximal end (P_s) of the stacked array of wafers **722"**. For example, as shown in FIG. **7**D, the wafers **702'"-***i* are coupled together at two points **762-1**, **762-2** on the proximal end (P_s) of the stacked array of wafers **722"**.

[0098] FIG. **8** illustrates a mitral valve implant **800**, having a shaft **804** with a proximal end (P) and a distal end (D). At the distal end (D) of the shaft **804** are a plurality of wafers **802-***i* forming a stacked array **822**. Each of the plurality of wafers **802-***i* is coupled to the shaft **804** such that the wafer **802-***i* is substantially perpendicular to the shaft **804**. An anchor **806** is coupled to a proximal end (P) of the shaft **806**. Although a cork-screw type anchor **806** is illustrated in FIG. **8**, any suitable anchor can be used with the shaft **804** to secure the mitral valve implant **800** to a patient's heart (not shown).

[0099] FIG. **9**A illustrates heart valve implant system **900**, in which an inflatable balloon **907** completely surrounds the stacked array of wafers **922**. FIG. **9**B schematically illustrates a heart valve implant **900'**, in which an inflatable balloon **907'** partially surrounds a portion or portions of the stacked array of wafers **922'**. The heart valve implant **900'** can have a plurality of wafers **902'**-I coupled to a shaft **904** and further having a balloon **907'**, which covers a subset of the wafers **902'-***i*. Similar to the previous embodiments, the implant system **900'**, shown in FIG. **9**B, includes an anchor **906** in the form of a cork-screw.

[0100] Alternatively or additionally, the balloon **907'** can surround a portion or portions of each one of the wafers **902'-***i*. The balloon **907'** can be configured to be inflated with a fluid, e.g., water or saline.

[0101] FIG. **10**A illustrates an example of a mitral valve implant **1000**. Implant **1000** includes a shaft **1004** and an inflatable balloon **1007**. The balloon **1007** comprises a proximal end (P_B) and a distal end (D_B). The distal end of the balloon D_B is furthest from an opening **1008**. The proximal end of balloon **1007** is at or near the opening **1008**. In this example, the balloon **1007** is shown as completely surrounding wafers **1002-***i*, so that each wafer is within a spacer cavity **1017** defined by balloon **1007**. However, in other embodiments, the balloon **1007** can surround one or some of the wafers **1002-***i*. the wafers **1002-***i* can provide internal structural support for the balloon **1007**. The incorporation of a balloon surrounding some or all of the wafers can be beneficial for use in patients whose current medical treatment and condition, or blood flow around the spacer, may be insufficient to allow for non-turbulent flow around and between wafers. Non-turbulent flow may lead to the creation of blood clots. Surrounding the wafers with a balloon can aid in reducing the surface area of the wafer exposed directly to the blood and allow for smoother and non-turbulent blood flow.

[0102] FIG. **10**B schematically illustrates a heart valve implant **1000** having one or more radiopaque markers **1040**. The one or more radiopaque markers **1040** can be attached to the shaft **1004** and positioned at or near the proximal end P_B of the balloon **1007**. Additionally or alternatively, the one or more radiopaque markers **1040** can be positioned at or near the distal end D_B of the balloon **1007**. Further, the one or more radiopaque markers **1040** can be positioned at or near the proximal P_B and distal D_B ends of the balloon **1007**.

[0103] Additionally and/or alternatively, the one or more radiopaque markers **1040** can be incorporated in the bodies of the wafers **1002-***i* to aid in the visualization of the movement of the implant **1000** during insertion and use. As will be appreciated by one of skill in the art, the one or more radiopaque markers **1040** can assist a physician in performing the methods described herein. For example, using known techniques (e.g., x-ray, fluoroscopy, etc.), a physician can use the radiopaque biomarkers **1040** to confirm correct placement and/or operation of the implant **1000**.

[0104] The shaft **1004** can include a lumen **1014**, which is in fluid communication with the spacer cavity **1017**. For example, the shaft **1004** can extend to at least a proximal end (e.g., at or near opening **1008**) of the balloon **1007**. Alternatively and/or additionally, the shaft **1004** can extend through a proximal end P_B of the balloon **1007**. Further, as illustrated in FIG. **10**B, the shaft **1004** can be attached to the distal end D_B of balloon **1007** and extend through the proximal end P_B of the balloon **1007**.

[0105] Any or all of the portions of the implants described herein can be formed from any biologically acceptable material. For example, materials such as Elast-Eon™ material can be used. At least the walls of balloon **1007** can be formed of a resiliently deformable biologically acceptable material.

[0106] The first (e.g., proximal P_B) end of the wall of balloon **1007** can be coupled, mounted, integrally formed with or otherwise secured to a portion of the shaft **1004**. The implant **1000** can also include an opening **1008**, proximate to the point of connection of the balloon with the shaft **1004**. This opening **1008** can fluidly connect the lumen **1014** of the shaft **1004** with the cavity **1017** of balloon **1007**. This connection can be used to direct a fluid (such as, but not limited to, saline or the like) through the lumen of the shaft into a the balloon cavity **1017** (e.g., from an inflation device (not shown)). Any suitable inflation device known in the art can be used. For example, the inflation device can be a syringe assembly. The opening **1008** can be a component (e.g., an integral part) of the balloon **1007** and/or can include an extension of the shaft **1004**.

[0107] The cavity **1017** can be defined by the opening **1008** and the walls of the balloon **1007**. The distal end D_B of the balloon **1007** can include an end plug **1009** that seals the distal end D_B of balloon **1007**. Alternatively or additionally, the distal end D_B of balloon **1007** can be formed of a continuous piece of material such that the spacer cavity **1017** is naturally sealed at the distal end of balloon **1007**.

[0108] A surgeon may selectively expand and/or retract the balloon **1007** and the spacer cavity **1017** by injecting and/or withdrawing an expansion or inflation medium into and from the spacer cavity **1017** (e.g., via lumen **1014**). Once the spacer cavity **1017** is inflated to a desired degree, the degree of inflation can be maintained by an inflation device, which can be configured to limit or prevent the withdrawal of expansion or inflation medium from the spacer cavity **1017** by plugging or backstopping the lumen **1014** at a proximal end (P) of the shaft **1004**.

[0109] Although, the implants described herein have been disclosed in the context of a mitral valve implant, an implant consistent with the present disclosure can also suitably be employed in other applications. For example, the implants described herein can be used with other valves of the heart, etc. For example, the size of the implant and/or the size of the wafers can be adjusted to configure the implant for use

with a different heart valve (e.g., the aortic valve). The present disclosure should not, therefore, be construed as being limited to use for reducing and/or preventing regurgitation of the mitral valve.

[0110] Other features and aspects of the various embodiments can also suitably be combined and/or modified consistent with the present disclosure. The disclosure herein should not, therefore, be limited to any particular disclosed embodiment, and should be given full scope of the appended claims.

What is claimed:

1. A heart valve implant comprising:
- a shaft having a first end and a second end;
- an anchor coupled to the first end of the shaft, the anchor configured to secure the heart valve implant to a patient's heart; and
- a plurality of wafers, wherein each of the plurality of wafers is coupled to the second end of the shaft to form a stacked array of wafers.

2. The heart valve implant of claim **1**, wherein the stacked array of wafers is configured to at least partially restrict a flow of blood through the heart valve during systole upon contact with at least a portion of a valve leaflet of the heart valve.

3. The heart valve implant of claim **2**, wherein the stacked array of wafers comprises a compliant surface.

4. The heart valve implant of claim **1**, further comprising an inflatable balloon, wherein said balloon surrounds at least a portion of the plurality of wafers.

5. The heart valve implant of claim **4**, wherein the balloon is at least partially inflated with a fluid.

6. The heart valve implant of claim **1**, wherein one or more of the plurality of wafers comprises a biocompatible polymer.

7. The heart valve implant of claim **6**, wherein the biocompatible polymer comprises a polyurethane, a polyethylene terephthalate (PET) and polyethyleneoxide (PEO) block copolymer, a polystyrene and poly(1,4-butadiene) block copolymer, a triblock copolymer made from poly(2-methyl-2-oxazoline) and polytetrahydrofuran, a polysiloxane, a polyether, or a combination thereof.

8. The heart valve implant of claim **1**, wherein one or more of the plurality of wafers comprises a shape memory material.

9. The heart valve implant of claim **8**, wherein the shape memory material comprises nitinol.

10. The heart valve implant of claim **1**, wherein the stacked array of wafers exhibits a tapered shape extending from a proximal end to a distal end.

11. The heart valve implant of claim **1**, wherein the stacked array of wafers exhibits a diamond-like shape.

12. The heart valve implant of claim **1**, wherein the plurality of wafers have variable cross-sectional diameters.

13. The heart valve implant of claim **12**, wherein the cross-sectional shape of the stacked array of wafers includes at least one of round, pear-shaped, elliptical, hour-glass shaped, triangular, or heart shaped.

14. The heart valve implant of claim **1**, wherein the plurality of wafers have substantially equal cross-sectional diameters.

15. The heart valve implant of claim **14**, wherein the cross-sectional shape of the stacked array of wafers includes at least one of rectangle or square.

16. The heart valve implant of claim **1**, wherein each of the plurality of wafers is slidably coupled to the shaft.

17. The heart implant of claim **1**, wherein each of the plurality of the wafers is fixedly coupled to the shaft.

18. The heart valve implant of claim **1**, further comprising a plurality of coupling members, wherein each of the plurality of coupling members is configured to couple at least one of the wafers to the shaft.

19. The heart valve implant of claim **1**, further comprising one or more radiopaque markers.

20. The heart valve implant of claim **19**, wherein the one or more radiopaque markers are disposed on the shaft, one or more of the plurality of wafers, or a combination thereof.

21. The heart valve implant of claim **1**, wherein the anchor comprises at least one barb, a helical feature, at least one anchor pad, or a combination thereof.

22. The heart valve of claim **1**, wherein said implant is a mitral valve implant.

23. A method of delivering a heart valve implant, the method comprising:
- implanting the heart valve implant in a patient's heart, the heart valve implant comprising:
  - a shaft having a first end and a second end;
  - an anchor coupled to said first end of said shaft, the anchor configured to secure the heart valve implant to heart tissue; and
  - a plurality of wafers, wherein each of the plurality of wafers is coupled to the second end of the shaft;
- at least partially collapsing said plurality of wafers of said heart valve implant;
- wherein implanting the heart valve implant comprises:
  - percutaneously inserting said heart valve implant into the heart;
  - securing said anchor of said heart valve implant to native coronary tissue of the heart; and
  - expanding the plurality of wafers to form a stacked array of wafers at least partially within a heart valve to at least partially restrict a flow of blood through a heart valve during systole upon contact with at least a portion of a valve leaflet of the heart valve.

24. The method of claim **23**, wherein said step of percutaneously inserting the heart valve implant comprises using a catheter.

25. The method of claim **24**, further including inserting the collapsed plurality of wafers into a lumen of the catheter and delivering said heart valve implant to a ventricle of the heart via said catheter.

26. The method of claim **23**, further including securing the heart valve implant to any of an interior surface of the heart, an exterior surface of the heart, or a combination thereof.

27. The method of claim **23**, wherein one or more of the plurality of wafers comprises a biocompatible polymer.

28. The method of claim **23**, wherein one or more of the plurality of wafers comprises a shape memory material.

29. The method of claim **28**, wherein the shape memory material comprises nitinol.

30. The method of claim **23**, wherein the stacked array of wafers comprises a distal end and an proximal end.

31. The method of claim **23**, wherein the heart valve implant further comprises an inflatable balloon that surrounds at least a portion of the plurality of wafers.

32. A method of delivering a heart valve implant, the method comprising:

percutaneously inserting a heart valve implant into a patient's heart, wherein the heart valve implant comprises a shaft extending from a first end to a second end, an anchor coupled to the first end of the shaft, and a plurality of wafers coupled to the shaft in proximity of the second end of the shaft, and wherein said wafers are in an at least partially collapsed state;

securing said anchor of said heart valve implant to native coronary tissue; and

expanding the plurality of wafers to form a stacked array of wafers disposed at least partially within the heart valve so as to at least partially restrict a flow of blood through the heart valve during systole.

* * * * *